

32. (Amended) The method according to claim 30 wherein said coating  
further comprises a polymer.

#### REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1-36 were pending. As noted above, Applicants have canceled claims 21-29 without prejudice to the filing of any divisional, continuation, or, continuation-in-part application. Claim 32 has been hereby amended for mere editorial purposes to correct an obvious typographical error and not for reasons of patentability. No new matter has been added. Therefore, claims 1-20 and 30-36 are currently pending.

In addition, Applicants respectfully request, as previously made of record, consideration of claims to additional species that are written in dependent form or other wise include all limitations of an allowed generic claim, as provided by 37 C.F.R. §1.141.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

#### **REJECTION UNDER U.S.C. §102(e)**

In the Office Action dated August 2, 2002, claims 1-3, 9, 12, 13, 15-20, 30, 31, and 33 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,968,092 (Buscemi *et al.*). In particular, it is alleged that Buscemi *et al.* disclose a tubular and cylindrical balloon-expandable stent, which releases drugs that promote epithelial cell growth. Furthermore, it is alleged that cell growth promoting drugs inherently induce or accelerate an *in vivo* fibrotic reaction, which would cause the stent to adhere to vessel walls. It is also alleged in the Office Action that Buscemi *et al.* disclose a coating that delays the onset of adhesion or fibrosis. Finally, it is alleged that Buscemi *et al.* disclose a method of manufacturing an adhesive stent graft according to the instant invention.

Applicants respectfully traverse this ground of rejection and submit that Buscemi *et al.* fail to meet every limitation of the instant claims and, therefore, fail to anticipate the claimed invention. As described in the specification (*see, e.g.*, specification at page 1, lines 12-20; at page 20, line 1 through page 22, line 10) and recited in the claims, the instant invention is directed, in pertinent part, to a stent graft comprising an endoluminal stent and a graft, wherein the stent graft releases an agent that induces the *in vivo* adhesion of the stent graft to a vessel wall. Applicants respectfully submit that Buscemi *et al.* fail to teach or suggest a stent graft, as further explained below.

Buscemi *et al.* merely disclose coated biodegradable stents, which are a very different medical device than a stent graft. More specifically, stents are small devices that can be inserted into a body passageway (*e.g.*, coronary artery, biliary duct) to expand, hold open, and/or prevent obstruction of the body passageway. Typically, a stent has metal tines that form a tubular web or open weave, which can be coated with a desired drug, as was known in the art and provided in Buscemi *et al.* (*see* Buscemi *et al.* columns 11 and 12). Therefore, stents act a support structures and need not be fluid-tight. Generally, stents are coated with drugs to prevent the growth of material through the stent tines, thereby preventing stenosis or restenosis (*i.e.*, build up that can lead to narrowing or re-narrowing of the lumen of a body passageway). In contrast, a stent graft comprises a graft (*e.g.*, a tube that can function as an alternate body passageway) that has stents to permit attachment of the graft to a body passageway. Hence, the graft material of a stent graft is selected to prevent the flow of fluids from the inside of the graft to the outside of the graft. For example, as described in the instant specification, a stent graft can be used to effectively bypass a damaged body passageway (*e.g.*, an aneurysm) while still allowing fluids to flow through the lumen of the graft but not through the graft walls (*see* specification, at page 19, line 10 through page 21, line 18). Thus, a coated biodegradable stent disclosed by Buscemi *et al.* could not be used to bypass a damaged body passageway because body fluids would not be rerouted through an alternate passageway and because body fluids could rush through the stent tines. Thus, Buscemi *et al.* fail to teach or suggest a stent graft according to the instant invention.

Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. §102(e) be withdrawn because the instant claims are patentably distinct over Buscemi *et al.*

#### **REJECTION UNDER 35 U.S.C. §103(a)**

In the Office Action, claims 1-4, 9, 11-20, 30, 31 and 33 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,361,780 (Ley *et al.*) in view of U.S. Patent No. 5,695,517 (Marin *et al.*). More specifically, it is alleged that it would have been obvious for a person having ordinary skill in the art to make the stent of Marin *et al.* having the collar of Ley *et al.* to treat a tubular area or a bifurcated area of a vessel according to the instant invention.

Applicants respectfully traverse this ground of rejection and submit that Ley *et al.* and Marin *et al.*, taken alone or in combination, fail to teach or suggest the claimed invention and, further, would not have motivated a person having ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success. The present invention is directed, in pertinent part for this rejection, to a stent graft comprising an endoluminal stent and a graft, wherein the stent graft releases an agent that induces the *in vivo* adhesion of the stent graft to a vessel wall. In particular, Ley *et al.* merely disclose a drug delivery collar or annulus made of a porous biocompatible solid that can be used in combination with another medical device (*e.g.*, stent). Thus, similar to Buscemi *et al.* discussed above, Ley *et al.* fail to teach or suggest a stent graft according to the instant invention. Ley *et al.* merely disclose a porous device that would not function as a graft. Furthermore, Ley *et al.* disclose that various types of drugs, such as growth stimulators or growth inhibitors, could be used as *therapeutic* or *diagnostic* agents. Thus, contrary to the assertion in the Office Action, Ley *et al.* fail to teach or suggest an agent that induces the *in vivo* adhesion of a stent graft to a vessel wall.

Applicants respectfully submit that the disclosure of Marin *et al.* fails to remedy the deficiencies of Ley *et al.* and, therefore, the combination of Ley *et al.* with Marin *et al.* fails to teach or suggest the instant invention. Marin *et al.* merely disclose an improved method of deploying an endoluminal graftstent and a modified vascular stent having a non-circular cross section. However, Marin *et al.*, while disclosing the use of a stent graft, fail to teach or suggest the use of a vessel wall irritant, much less any type of agent that induces the *in vivo* adhesion of a

stent graft to a vessel wall according to the instant invention. In addition, Marin *et al.* teach away from the use of any type of biological agent because the graftstent seal with the vessel wall is preferably hemostatic (*see*, Marin *et al.* at column 3, lines 32-35, and at column 4, lines 23-25). Moreover, the teaching of Marin *et al.* is merely cumulative subject matter, as the instant specification discloses several exemplary stent grafts (*see*, specification at page 7, line 4 through page 8, line 2).

Overall, Marin *et al.* fail to provide a motivation or suggestion to modify the disclosures of Marin *et al.* and Ley *et al.* to arrive at the instant invention. Applicants respectfully submit that the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination (*see, e.g., In re Mills*, 16 USPQ2d 1430, Fed. Cir., 1990; *In re Fritch*, 23 USPQ2d 1780, Fed. Cir., 1992). Thus, the combined cited prior art does not render the claimed invention obvious.

Applicants respectfully submit that the Office Action has not set forth a *prima facie* case of obviousness, where the cited references fail to teach every limitation of the instant invention and fail to provide motivation for a person having ordinary skill in the art to modify or combine the prior art teachings to arrive at the claimed invention with a reasonable expectation of success. Accordingly, Applicants respectfully submit that the claims distinguish patentably over Ley *et al.* and Marin *et al.*, and, therefore, satisfy the requirements of 35 U.S.C. § 103(a). Applicants request that this rejection be withdrawn.

All of the claims pending in the application (claims 1-20 and 30-36) are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.



00500

PATENT TRADEMARK OFFICE

(JCP:imp) 318045

Phone: (206) 622-4900

Fax: (206) 682-6031

Respectfully submitted,

Seed Intellectual Property Law Group PLLC

A handwritten signature in black ink, appearing to read "Jeffrey C. Pepe", written over a horizontal line.

Jeffrey C. Pepe, Ph.D.

Registration No. 46,985

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 21-29 have been canceled without prejudice.

Claim 32 has been amended as follows:

32. (Amended) The method according to claim 30 wherein said ~~agent~~  
coating further comprises a polymer.

318045